Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 101: February 16 - 17, 2005

Committee Members
Dr. Gary Overturf, Chair
Dr. Ruth A. Karron
Dr. David Markovitz
Ms. Cindy Lyn Province, R.N., M.S.N.*
Dr. Walter Royal III
Dr. Monica M. Farley
Dr. Philip S. LaRussa
Dr. Steven Self
Dr. Bonnie M. Word

FDA Participants
Dr. Roland Levandowski
Dr. Zhiping Ye
Dr. Mary Foulkes
Dr. Jerry Weir
Dr. Richard Walker
Dr. Richard Pastor

Consultants
Dr. Robert Couch
Dr. Walter Dowdle
Dr. Pamela McInnes
Dr. Theodore Eickhoff
Dr. Arnold Monto
Dr. Stephen Philips
Dr. Benjamin Schwartz
Dr. Melinda Wharton
Dr. Peter Palese

Guest Speakers
Mr. Albert Thomas, sanofi pasteur
Ms. Linda Canas, DOD
Dr. Nancy Cox, CDC
Dr. Keiji Fukuda, CDC

Executive Secretary
Christine Walsh, R.N.

Committee Management Specialist
Denise Royster

These summary minutes for the February 16 – 17, 2005 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____.

I certify that I participated in the February 16 – 17, 2005 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____
Christine Walsh, R.N.
Executive Secretary

_____
Gary D. Overturf, M.D.
Chair

*Consumer Representative

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on February 16 - 17, 2005 at the Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, MD. In open discussion on February 16, the committee reviewed and discussed the selection of strains to be included in the influenza virus vaccine for the 2005 – 2006 season. In open discussion on February 17, the committee heard a presentation on the update of the FDA Critical Path initiative and heard overviews of the Laboratory of Biophysics and the Laboratory of Pediatrics & Respiratory Viral Diseases.

Following is a summary of the open discussion. Additional information and specific details may be obtained from the transcript of the meeting. The transcript may be viewed on the World Wide Web at http://www.fda.gov/ohrms/dockets/ac/05acdocs.htm.

Open Session

The Vaccines and Related Biological Products Advisory Committee meeting was called to order by the Chair, Dr. Gary Overturf, on February 16, 2005 at 8:34 a.m. EST. Dr. Roland Levandowski, FDA, discussed last year's selection of the components of the influenza vaccine and the constraints, and importance and deadlines for the selection of this year's vaccine components. Subsequent presentations included U.S and world surveillance, vaccine responses and options, availability of strain reagents, and comments from manufacturers. An Open Public Hearing was announced. No public comment was offered.

In the afternoon, the panel heard an overview of options for strain selection of the components of next season's influenza vaccine. After discussion, the committee made the following recommendations for the influenza virus strains to be included in the vaccine for use during the 2005 – 2006 season in the United States. Based on information about the appearance and epidemiology of new influenza virus strains, responses to current vaccines, and the availability of new candidate strains for manufacturing, the committee recommended:

- The Committee unanimously recommended (17 votes in favor, 0 against, and 0 abstained) retaining the 2004 – 2005 influenza A H1N1 component, New Caledonia 20/99 for the 2005 – 2006 season.
- The Committee unanimously recommended (17 votes in favor, 0 against, and 0 abstained) changing the influenza A H3N2 to an A/California/7/2004-like virus for the 2005 – 2006 season.
- The Committee unanimously recommended (17 votes in favor, 0 against, and 0 abstained) retaining the 2004 – 2005 influenza B/Shanghai-like strain for the 2005 – 2006 season.

This completed the committee discussion and recommendations and Day 1 of the meeting was adjourned by the Chair at 3:51 p.m.

The Chair called Day 2 of the meeting to order at 8:38 a.m. EST. An Open Public Hearing was announced. Ms. Sadhana Dhruvakumar representing People for the Ethical Treatment of Animals made public comment. In open session, the Committee heard a presentation and made comment on the update of FDA Critical Path Initiatives. The Committee also heard overviews on the Laboratory of Biophysics and the Laboratory of Pediatric & Respiratory Viral Diseases.

This ended the open session on Day 2. The open session was adjourned at 10:32 a.m.